VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS CONSUMER PROTECTION AND FOOD SAFETY

Meat Inspection Service MONTPELIER, VT Chuck Ross, Secretary



MIS DIRECTIVE

13000.2, Revision 1

7/25/14

Adopted from FSIS Directive 13000.2 Rev. 1

PERFORMING SAMPLING TASKS IN OFFICIAL ESTABLISHMENTS USING THE PUBLIC HEALTH INFORMATION SYSTEM

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) for performing sampling tasks in official establishments related to FSIS domestic sampling programs using the Public Health Information System (PHIS). FSIS is reissuing this directive to incorporate the PHIS enhancements and changes associated with the sampling tasks.

KEY POINTS:

- Provides IPP instructions for submitting directed lab samples
- Provides IPP instructions for submitting collector generated samples
- Provides IPP instructions for entering KIS™ test results in PHIS
- Provides IPP instructions for sample collection in the PHIS disconnected state
- Describes the PHIS sampling enhancements

II. CANCELLATIONS

FSIS Directive 13,000.2 Performing Sampling Tasks in Official Establishments Using The Public Health Information System, 4/11/2011

III. BACKGROUND

- A. There are two basic types of laboratory sampling tasks in PHIS:
 - 1. Directed laboratory sampling which is automatically generated and filtered under Lab Sampling on the task list. Example is the NRP residue requests; and

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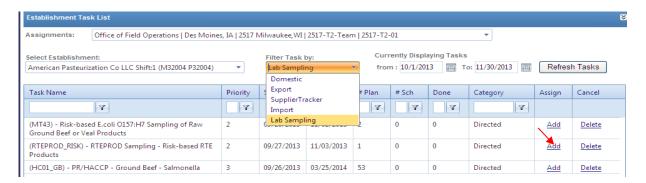
- 2. Collector generated (unscheduled) laboratory sampling which is generated by IPP. Example is tissue residue analysis in response to a positive in-plant KIS™ test.
- B. The PHIS User Guide provides step-by-step instructions for collecting samples based on different PHIS user roles. IPP, including Consumer Safety Inspectors (CSIs) and Public Health Veterinarians (PHVs), complete both directed residue sampling tasks and collector generated residue sampling tasks using PHIS.

IV. SCHEDULING A DIRECTED LABORATORY SAMPLING TASK

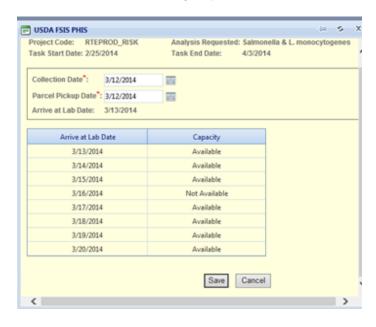
- A. PHIS displays sampling tasks on the Task List as soon as they are assigned. PHIS assigns most sampling projects monthly. PHIS assigns sampling tasks for routine sampling based on the information entered in the establishment profile, including slaughter data and historical sample collection data. Also, PHIS assigns follow-up sampling tasks in response to positive test results. When PHIS assigns a new sampling task, an alert appears on the inspector homepage for the majority of sampling tasks. IPP are to add sampling tasks to their Task Calendars and schedule the sampling task as soon as possible considering the establishment's production schedule. In multiple shift establishments, sampling tasks are visible to all assigned IPP. IPP are to coordinate with immediate supervisors to determine sampling responsibilities.
- B. To schedule a directed sampling task, IPP are to click on the **Task Calendar** on the left navigation menu.



- C. IPP are to go to Establishment Task List.
 - 1. IPP are to select the correct assignment from the Assignments drop-down list and select the correct establishment from the Select Establishment dropdown list.
 - 2. IPP are to click Add to schedule a sample on the task calendar.
 - 3. IPP are to select Lab Sampling from the Filter Tasks By drop-down list.



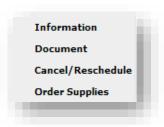
D. Upon clicking Add, a sample collection window will open. The Collection Date and Parcel Pickup Date default to the current date. IPP are to change the date forward, if needed. For example, second shift sample collection prevents parcel pickup until following day.



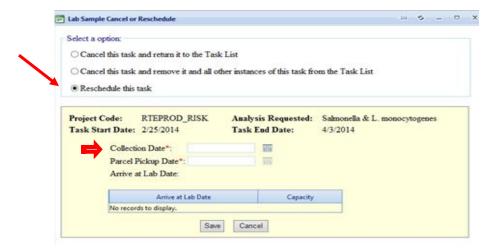
- E. Laboratory capacity limits are set by day of week, and many projects will have more capacity slots available earlier in the week. IPP are to schedule the sampling tasks to the task calendar using a realistic collection date based on the plant's production schedule. IPP are to schedule the task as soon as possible after receiving it to ensure a capacity slot is available for the desired collection date. Once the sampling task has been moved from the task list to the calendar, a capacity slot is reserved to accommodate the scheduled sample.
- F. IPP are to cancel or reschedule sampling tasks as soon as they become aware that they will not be able to collect the samples on a scheduled date, so that capacity slots can be released for others to use. If IPP wait to schedule a sampling task until the final days of the collection window, they may find that no lab capacity is available and receive a "**Not Available**" response.
- G. IPP are to schedule sampling for low-volume and infrequent producers as far in advance as possible.
- H. A "Not Available" lab capacity response will not appear for follow-up sampling.

V. RESCHEDULING OR CANCELLING A DIRECTED SAMPLING TASK

A. If IPP cannot collect the sample on the scheduled collection date, IPP are to change the collection date in PHIS.



B. IPP are to right click on the task to be rescheduled. When IPP click on the task to be rescheduled, the dropdown box, located above, will open. IPP are to select **Cancel/Reschedule** from the drop-down menu. Upon clicking on **Cancel/Reschedule**, the window below will open.



C. IPP are to click **Reschedule this Task** as soon as they are aware that the sampling task needs to be rescheduled and select a new Collection and Parcel Pickup Date. IPP are then to click **Save.** Upon clicking **Save,** a task will display on the selected collection date on the Task Calendar.



- D. IPP will have **two** options for cancelling the task.
 - 1. IPP are to click the first option to cancel the sampling task and return it to the task list.
 - 2. IPP are to click the second option if the task is to be removed, AND all other similar tasks are to be removed from the task list. This function cannot be reversed. For example, if three residue sample tasks were planned on the task list within the same collection window, and the IPP selects the option "Cancel this task and remove it and all other instance of this task from the task list", then all three residue tasks will be cancelled and removed from the task list.

VI. ORDERING SUPPLIES

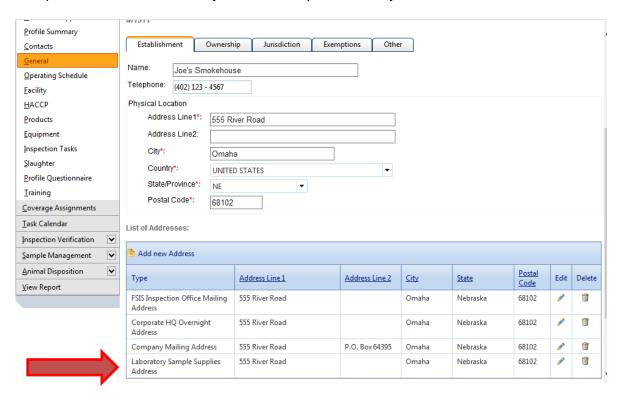
A. IPP are to right click on task and select **Lab Sample Order Supplies** from the dropdown menu. A pop-up window appears with two read only fields and one free text field. IPP are to enter text in the **Comments** field for the supplies request and click **Submit Request**. A confirmation message appears. IPP are to close the pop-up.



- B. IPP may also submit requests for sampling supplies through Outlook:
 - FSIS Sampling Supplies Western Lab
 - FSIS Sampling Supplies Midwestern Lab
 - FSIS Sampling Supplies Eastern Lab
- C. IPP can request supplies from any of the three FSIS Laboratories through Outlook for all sampling projects except KIS testing supplies. Requests for KIS supply requests are to be sent to the Midwestern Lab. However, if the KIS requests are made through the sample task option, PHIS will send the request to the appropriate lab based on the project code.
- D. IPP are to are to verify that the address for shipping laboratory sampling supplies is correct in PHIS when an "Update Establishment Profile" task is scheduled.
 - 1. If the establishment profile lists a Laboratory Sample Supplies Address, IPP are to verify that the physical street address (not a P.O. Box), city, state, and zip code are correct.
 - 2. If the establishment's Laboratory Sample Supplies Address is incorrect or includes a P.O. Box

number, IPP are to:

- a. Click on the **Edit** icon, remove the P.O. Box number (if applicable) and enter the correct physical street address, city, state, and zip code information of the establishment; and
- b. Click Save.
- 3. If the establishment's Laboratory Sample Supplies Address is not listed, IPP are to:
 - a. Click on Add New Address;
 - b. Select Laboratory Sample Supplies Address for Address Type dropdown menu choice; and
 - c. Complete the address line, city, state, and zip code. Verify the information is correct. Click Save.



VII. DIRECTED SAMPLE COLLECTION AND SUBMISSION

A. IPP are to right click on the task and select **Document.** The **Sample Mangement-Sample Collection** page opens. Enter the appropriate product information as described by the categories provided under the Generate a Sample tab. There may be subcategories after the initial selection. Click **Save and Continue**. The Sample Collection Data tab automatically opens.



B. IPP are to complete the information in the required fields on the **Sample Management-Sample Collection** page and click on **Save and Continue**.



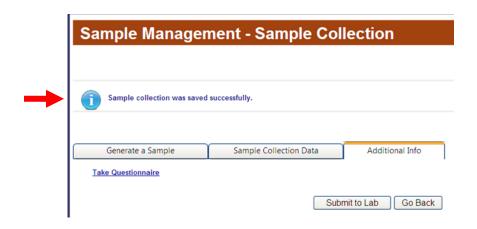
C. IPP will see a message (below) appear that sample collection data was saved successfully. The **Additional Info** tab automatically opens. Once IPP have collected the sample and documented the sample collection in PHIS, they are to click the **Print Form** link in the upper right corner of the **Sample Management-Sample Collection** page. IPP are to review the information for accuracy.

SAMPLE ANALYSIS REQUEST FORM



D. If the information is accurate, IPP are to click **Submit to Lab** to transfer the electronic record to the lab. IPP are to apply the bar code label from the sample seal set in the designated location at the top of the lab form and sign and date the form before placing the form in the shipping container. Instructions are provided in <u>FSIS Directive 7355.1</u>, Use of Sample Seals for Laboratory Samples and Other Applications.

NOTE: If IPP determine that inaccurate information is on the electronic lab record, IPP are to edit information on the record prior to posting it to LIMS-Direct and resubmitting it to the lab.

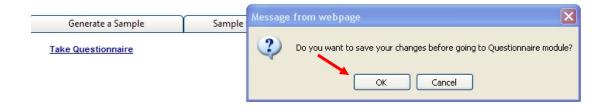


E. IPP are to click on the Take Questionnaire link.

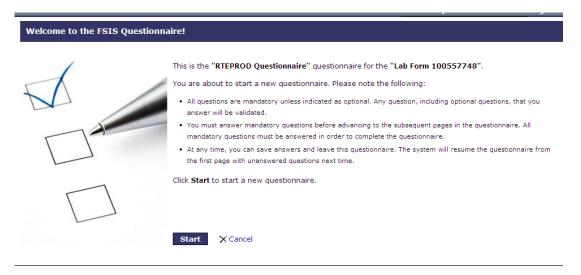


F. IPP are to click **OK** to save changes before proceeding to the questionnaire.

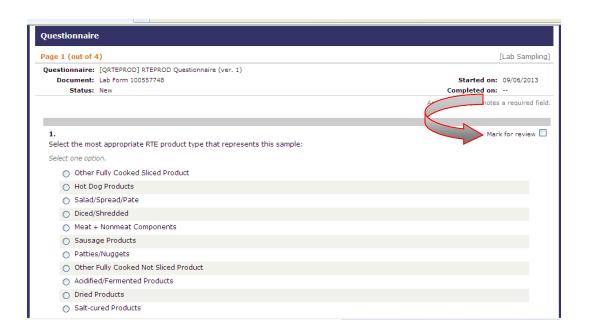
Sample Management - Sample Collection



G. IPP are to read the informational page and click Start.



H. IPP are to answer all the questions. If in doubt, IPP are to check the **Mark for Review** box in the upper right hand corner. IPP may research and answer them later.



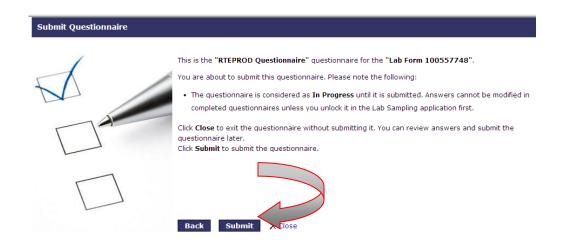
I. After IPP complete the questions, they are to click on **Next**. If IPP checked the **Mark for Review** box, these questions remain in a review status, and IPP are to click on **Save and Close**.



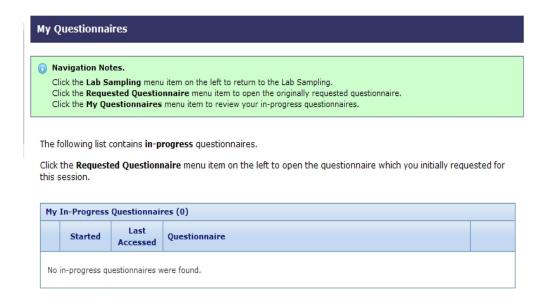
J. If IPP choose **Save and Close**, the "in progress Questionnaires" are displayed from the **My Questionnaires** menu option. IPP may return to **Lab Sampling** with the **Lab Sampling** menu option or open the original requested questionnaire with **Requested Questionnaire** menu option.



K. If IPP choose **Next**, the Questionnaire is finalized and ready to be submitted. If IPP need to review again, click **Back**. If not, IPP click **Submit**. If IPP click **Close**, the questionnaire is not submitted and IPP can review it later.



- L. The screen below confirms the questionnaire has been submitted. Once the questionnaire is submitted, a message will appear that states "no in-progress questionnaires were found." As a review, there are four choices at the end of the questions:
 - 1. Save and close saves the information entered as In Progress. Does not finalize or submit answers. IPP can return to the questionnaire at another time;
 - 2. Previous go back to previous screens to review or edit responses;
 - 3. Next takes IPP to final screen where they can finalize; and
 - 4. Submit submit the responses.



M. IPP are to close the PHIS sample collection window by clicking **X** in the upper right corner. After IPP have scheduled and submitted the task information, the **# sch** and **Done** columns of the **Establishment Task List** will both increase by one.

VIII. COMPLETING A DIRECTED LAB SAMPLING TASK SCHEDULED BY ANOTHER INSPECTOR

- A. To complete a sampling task scheduled by another inspector, IPP are to claim the sampling task by right clicking on the task and selecting **Document.** IPP will see the **Sample Management-Sample Collection** page. IPP are to click **Save.**
- B. IPP are to complete the required fields and click **Save and Continue.** IPP will see a confirmation message at the top of the page. If IPP see a third additional info tab, they are to answer all the required questions.
- C. IPP are to click **Submit to Lab**, and IPP will see a confirmation message.
- D. IPP are to click **Print Form.** An Adobe PDF window opens. Note the name has changed to the collector from the inspector that scheduled the sampling task and the form is accurate for submission with the sample.
- E. IPP are to close the PDF window and close the Lab Sampling window. IPP will see the Task Calendar page.

IX. ENTRY OF NEGATIVE IN-PLANT RESIDUE SCREENING RESULTS (KIS™ TEST)

A. For the entry of negative KIS[™] test results in PHIS, IPP are to go to **Animal Disposition** on the left navigation menu and then go to **Establishment Reporting** to open the Establishment Reporting page.



- B. IPP are to select the Establishment, correct date, shift, and type in the dropdowns and click **Continue**.
- C. All in-plant residue sample results and submissions start from the **Sub-Class Summary** page. To start the process, IPP are to add a new disposition or edit a disposition already in the system. At the **Sub-Class Summary** page, IPP are to click on the **Add Disposition Record** under the Edit column if they need to add a disposition. Otherwise, IPP are to click on the **Edit** icon for the disposition they plan to edit.



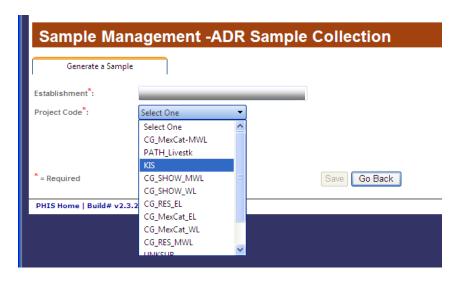
D. IPP will see the **Daily Disposition Record Detail** page open (top/bottom displayed below).





E. IPP are to click on the **Add Lab Sample Collection** link located at the bottom of the page, and the **Sample Management-ADR Sample Collection** page opens.

NOTE: IPP have the option of using in-plant negative templates to assist with the entry of similar negative KIS results. A list of eight negative in-plant templates may be viewed beneath the broken line in the figure above. Templates may be used to save time when entering negative results with the same condition. For example, after clicking on the **Edit** icon for the animal with arthritis from the list of dispositions, the screen above opens. There is an available template at the bottom for arthritis. Select the template by clicking the **Copy** (clipboard) icon. Another lab sample will be generated at the bottom of the window. Select the **Edit** icon for this animal in order to submit the lab sample. The tag number for the particular animal travels with the template.



- F. IPP are to select **KIS**™ test from the Project Code dropdown, wait for the additional box to open, and enter the day's date. The selected record's number will display by default.
- G. IPP are to enter the residue case number, if there is a case number, and in the Reason Code dropdown, they are to select the correct reason for sampling.

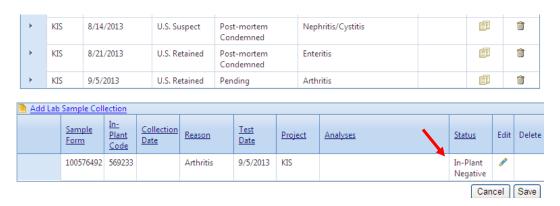
H. In the Result dropdown, IPP are to select **Negative**.



I. IPP do not complete the **Analyses and Select Sample** check boxes for a negative test. Refer to the screenshot in section VII.E.



J. IPP are to click the **Save** button. IPP have the option to click **Save as Template**. IPP will see the **Sample Management-ADR Sample Collection** page. The top of the page reports "Your negative sample result has been recorded for reporting purposes. The results will not be sent to a lab." IPP are to click **Go Back** and then exit the page to enter results for another sub-class.

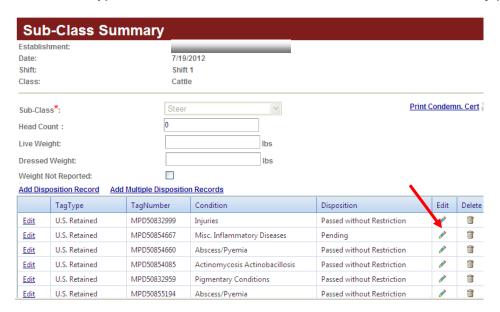


X. ENTRY OF POSITIVE IN-PLANT RESIDUE SCREENING RESULTS

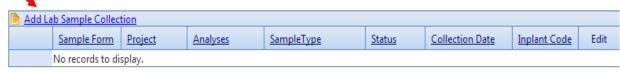
- A. For the entry of positive KIS[™] test results in PHIS, IPP are to go to the **Animal Disposition** navigation menu tab.
- B. IPP are to go to **Establishment Reporting** tab and start at the **Class Summary List** and click on the **Edit** pencil to open the **Class Summary Information** page.



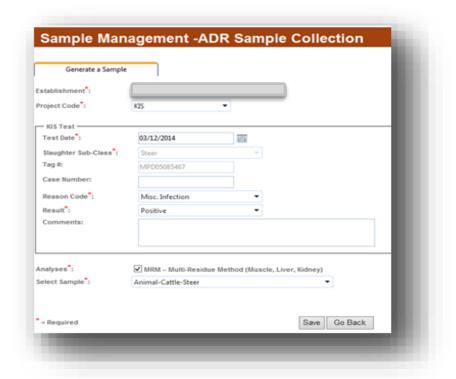
C. IPP are to click on the type of Sub-Class, and IPP will see the **Sub-Class Summary** page.



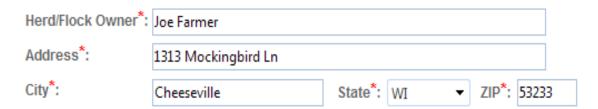
D. IPP are to either add a new disposition or edit a disposition already in the system by clicking the **Edit** pencil icon for the disposition that will be edited. IPP will see the **Daily Disposition Detail Record** page.



E. IPP are to click on the **Add Lab Sample Collection** link and will see the **Sample Management-ADR**. Sample Collection window below.



- F. IPP are to select KIS, and the selected record's date and tag number will display by default.
- G. IPP are to enter the requested information and select "positive" from the **Result** dropdown.
- H. When IPP see the additional fields **Analyses** and **Select Sample**, they are to check the box for the appropriate analyses and sample.
- I. IPP are to click the **Save and Continue** button. IPP will see the **Sample Management-ADR Sample Collection** page. Because the sample was positive, IPP are to schedule sample collection.
- J. IPP are to click the **Schedule Sample** link, and the **Schedule Lab Sample Task** (yellow box in previous section) pop-up window will open.
- K. The **Collection and Parcel Pickup** dates default to the current date. IPP are to change the dates, if needed, click the **Save** button, and complete the required Collection/Animal Information.



L. If there is a foreign address, IPP are to click on the **Foreign Address** box and select a country and province from the dropdown lists.

- M. IPP are to complete Animal Information fields that are marked with red asterisks. The address defaults to the establishment address. IPP are to update the address to the herd/flock owner's address. However, if the owner's address is not known at the time of sample collection, IPP are to submit the establishment's address. If IPP obtain owner information on violative results later, they are to send the information to Residue@fsis.usda.gov, fax it to 402-344-5008, or call 1-800-233-3935.
- N. IPP are to click **Save and Continue**. The **Additional Info** tab appears for IPP to **Take Questionnaire**. If there is no tag number, IPP are to enter "no tag."

SAMPLE ANALYSIS REQUEST FORM				
For Lab Use (Only	Place Sample Seal Label Here		100734260
COLLECTION INFORMATION				
1. SAMPLE FORM ID:	100734260	7. ESTABLISHMENT ID:		
2. PROJECT CODE:	KIS	8. ESTABLISHMENT NAME:	_	
3. SAMPLE SOURCE:	Animal-Cattle-Steer	9. COLLECTION DATE:	03/03/2014	
4. ANALYSIS:	MRM – Multi-Residue Method (Muscle, Liver, Kidney)	10. SHIPMENT DATE:	03/03/2014	
		11. COLLECTOR NAME:	Carlos Gomez	
		12. COLLECTOR PHONE:	619-344-5000	
5. ASSIGNED LAB:	Midwestern Laboratory	(St. Louis,MO)		
6. DISTRICT/CIRCUIT:	05 - Alameda, CA / 0525			
ANIMAL INFORMATION				
13. SLAUGHTER DATE:	03/03/2014	21. HERD/FLOCK OWNER:	Joe Jones	
14. TAG NO:	MPD12345555	22A. ADDRESS LINE 1:	13677 Yorba	Ave.

- O. IPP are to print a copy of the lab form and review information for accuracy when all the questions are answered, and a confirmation message appears that "no in-progress questionnaires were found." When they complete their review, IPP are to click **Submit to Lab**.
- P. After clicking **Submit to Lab**, IPP are to place the bar-coded label from the sample seal set in the designated area, **sign and date** the form, and submit it with the sample tissues to the lab. As previously noted, IPP may edit inaccurate data on the electronic record after submission, but they need to do so before posting it to LIMS-Direct.

XI. SUBMITTING APHIS SAMPLES FOR TB, BRUCELLOSIS, OR BSE TESTING

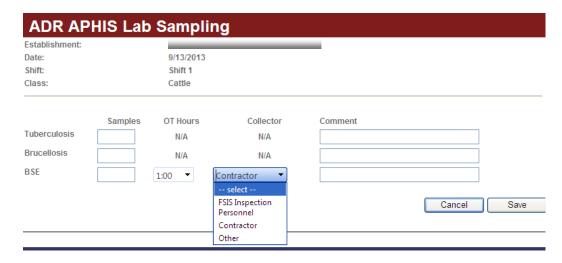
A. IPP are to start with the Class Summary List page (refer to XI, A-D) and click on the Edit pencil.



B. IPP will see the **Class Summary Information** page, which will display the previously entered Inspected Slaughter records and their associated sub-classes, head counts, and live and dressed weights. IPP are to click on **APHIS Lab Sampling** link.



C. IPP will see the **ADR PHIS Lab Sampling** page and are to fill in the type of sample for collection. For a BSE sample, IPP are to select the time for sample collection and the collector from the drop down menu and click **Save.**

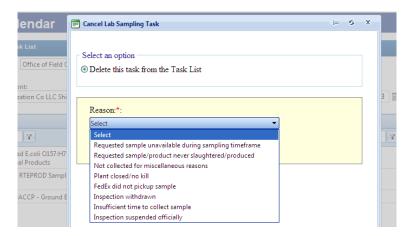


XIV. DELETING A SAMPLE TASK FROM THE TASK LIST

A. In situations where IPP cannot collect a sampling task within the designated time frame (e.g., product not being produced during the sampling window for a directed sampling task), and the task has not been scheduled, IPP are to delete the task from task list. IPP are to:

1. Click on Task Calendar in the left navigation menu. Go to Task List;

- 2. Select the correct assignment from the **Assignments** dropdown list;
- 3. Select the correct establishment from the **Select Establishment** dropdown list:
- 4. Select **Lab Sampling** from the Filter tasks dropdown list;
- 5. Find the sampling task that has "0" scheduled, and "0" done;



- 6. Click **Delete** in the far right column. A pop-up window appears;
- 7. Select an appropriate reason from the drop-down list; and
- 8. Click Submit Task for Cancelling. Sampling tasks no longer appears on the task list.

NOTE: All sampling tasks for that project code will be deleted from the task list.

XV. COLLECTING A SAMPLE IN THE DISCONNECTED STATE

A. When internet connectivity is limited or not available at an establishment, the disconnected state allows IPP to perform certain functions of the sample collection task. However, PHIS cannot interact with the laboratory reservation system or transmit sample collection information to the laboratories. IPP are to:

- 1. Schedule the sampling task on the task calendar while connected to the internet;
- 2. Determine when the establishment is likely to produce the product to be sampled;
- 3. Determine when there is time to return to a location with internet connectivity to record and submit the sample information in PHIS; and
- 4. Schedule sample collection when they are able to access an internet connection, enter, and submit sample information in PHIS within 24 hours of sample shipment.
- B. Before IPP leave an establishment with internet connectivity to perform the sample collection at an establishment without connectivity, IPP are to:
 - 1. Open the scheduled sampling task in PHIS;
 - 2. Enter available information about the scheduled task; and

- 3. Print two copies of the sample form and take both copies to the establishment without connectivity.
- C. After arriving at an establishment without connectivity, IPP are to collect the sample and are to:
 - 1. Document any remaining necessary information by hand on both copies of the printed sample form;
 - 2. Sign one copy of the sample form and place it in the shipping container with the sample;
 - 3. Close and seal the shipping container with the sample and signed sample form inside before leaving the establishment;
 - 4. Follow normal shipping instructions. IPP are not to remove any unsealed shipping container with a sample in it from the establishment; and
 - 5. Keep the second sample form as a record of the sample collection information to be recorded in PHIS later.
- D. IPP are to return to an establishment with internet connectivity within 24 hours and are to:
 - 1. Log into PHIS, select the sampling task from the task calendar, and document the sample information recorded on the printed copy of the sample form; and
 - 2. Submit the electronic record to the laboratory by clicking **Submit to Lab** after completing data entry. The sampling task will now change to "Completed" on the task calendar.

XVI. REPORTING SAMPLE RESULTS

FSIS negative and positive sample results and additional sample results information are accessible through the Establishment Profile Summary page and through the Dashboard on the Inspector homepage. IPP and EIAOs can access FSIS sample results through LIMS-Direct EIAOs will continue to receive FSIS positive sample results through the Biological Information Transfer and Email System (BITES).



XII. DATA ANALYSIS

The Data Analysis and Integration Staff (DAIS) within the Office of Data Integration and Food Protection (ODIFP) will review PHIS sampling data for the various sampling projects to assess sample collection, nonresponse, and discard rates. Results will be shared with the Office of Field Operations (OFO) and the Office of Policy and Program Development (OPPD) to inform future FSIS guidance and policy.

XIII. QUESTIONS

Refer questions regarding this directive to the Policy Development Staff or Risk Innovations and Management Staff through <u>askFSIS</u> or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter Directive 13,000.2

Question Field: Enter question with as much detail as possible. Product Field: Select **Sampling** from the drop-down menu. Select **Sampling** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

Assistant Administrator

Office of Policy and Program Development

Katherine M. Marbonara DVM

Head of Service

VT Meat Inspection Service